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10/564,083	01/11/2006	Tatsuhisa Watanabe	050779	7273

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KRATZ, QUINTOS & HANSON, LLP
1420 K Street, N.W.
Suite 400
WASHINGTON, DC 20005

EXAMINER	
RIGGS II, LARRY D	
ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/564,083	WATANABE ET AL.	
	Examiner	Art Unit	
	LARRY D. RIGGS II	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11 January 2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment filed 11 January 2006 are acknowledged and entered.

Status of Claims

Claims 1-17 are cancelled. Claims 18-34 are currently pending and under consideration.

Information Disclosure Statement

The information disclosure statement filed 11 January 2006 is acknowledged. A signed copy of the corresponding 1449 form has been included with this Office action.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-34 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The recent en banc decision regarding Bilski v. Warsaw (2008) set forth that a process is patent-eligible if (1) it is ties to a particular machine or apparatus or (2) it transforms a particular article into a different state or thing.

The instant claims are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination as well as a general computer program product containing a program to said method and a general

apparatus for carrying out said method. The instant claims are drawn to the abstract process steps of receiving present and previous data, storing a plurality of reference patterns, selecting a reference pattern matching the present data and previous data, calculating a value indicative of a distance between a position between the reference patterns and determining a validity of the present data.

The instant method claims 26-34 do not recite or inherently involve any transformation of an article, therefore the Examiner must determine if the instant claims have a tie to a particular machine or apparatus. Instant claims do not recite any limitation that ties the recited abstract process to any particular machine or apparatus. Further, claim 34 only recites a computer readable medium comprising executable instructions for carrying out said abstract process, and therefore reads on a general apparatus that would preempt the abstract process. Similarly, claims 18-25 recite a device carrying out said abstract process. As such, the device is not a particular machine or apparatus because the instant claims fail to recite structural elements of any machine or device and, further, its only function would preempt the abstract process as set forth above.

Nominal or token recitations will not suffice, E.g. displaying, inputting, obtaining, See Ex parte Langemyr (May 28, 2008). Applicants are cautioned against introduction of new matter in an amendment.

Since the instant claims 18-34, do not provide a physical transformation, the Examiner must determine if the instant claims produce a tangible final result. For a

claim to be "tangible", the claim must set forth a real-world final result. Furthermore, the claim must recite a tangible final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

Method claims 26-34 do not produce a tangible final result. A tangible requirement requires that the claim must set forth a tangible form of the amount of bacteria from water to produce a real-world result. The instant claims are drawn to a method of confirming a validity of result of clinical examination of a part of a subject for a clinical examination. However, the last step of the claim determines a validity of the present data based on a value, the result of the invention is a set of valid data, which, in itself, is not tangible. Since the claim itself must include a tangible final result, the instant claims are non-statutory.

Regarding the device claims 18-25, and the computer program product containing a program of claim 34, because the method claims are drawn to nonstatutory subject matter for not producing a tangible result, the device and computer program product that perform the process also do not produce a tangible result, thus also drawn to nonstatutory subject matter.

This rejection could be overcome by amendment of the claims to recite that a specific final result of the process is outputted to a user, or by including a result that is a physical transformation. The applicants are cautioned against introduction of new matter in an amendment.

For these reasons, claims 18-34 are considered non-statutory subject matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 18, 19, 22-27 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Toshiba (EP 0389992).

The instant claims provides a method and device of confirming a validity of result of clinical examination of a part of a subject for a clinical examination comprising steps of receiving present and previous data, storing a plurality of reference patterns classified into a plurality of levels, selecting a reference pattern matching the present data and previous data, calculating a value indicative of a distance between a position between the reference patterns and determining a validity of the present data.

Regarding claims 18, 22, 26, 30, Toshiba shows a method and apparatus for analyzing the validity of medical examination data, (page 2, lines 27-40; Figures 1-2). Toshiba shows receiving thousands of sets of present and previous medical examination data with corresponding teaching data stored in order of acquisition, (page 4, lines 30-33), examination and teaching data grouped (pattern) and corresponding (matched), (page 5, lines 14-20), calculating a value indicative of a distance between a first and second reference wherein the value determines the validity of each medical examination data, (page 4, lines 1-26).

Regarding claims 19, 27, Toshiba shows each set of medical examination data corresponding to a specifically modified teaching data, (page 4, lines 30-57).

Regarding claims 23, 31, Toshiba displays when the medical examination data does not meet a particular value and there is a need for a re-examination, (page 4, lines 19-26).

Regarding claims 24, 32, Toshiba shows stored groups of teaching data that correspond to a particular group of medical examination data, (page 5, lines 19-28).

Regarding claims 25, 33, Toshiba shows stored ranges of values that the value of the medical examination data corresponding teaching data can be compared, (page 6, lines 27-33).

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 18-20, 22-28 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al., (EP 0389992) as applied to claims 18, 19, 22-27 and 30-33 above, in view of Ioki et al. (Japan Association of Medical Information, 2002, 14 November, 211-213), IDS, received 11 January 2006.

The instant claims 20 and 28 depend from claims 18 and 26 respectively, with the extra limitation that the reference patterns include image data.

Toshiba is applied to claims 18, 19, 22-27 and 30-33 above.

Toshiba does not show reference patterns that include image data.

Ioki et al. shows the relationships between leukocyte-scattergrams and clinical data, (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination by Toshiba by comparing the medical examination data with leukocyte-scattergrams of Ioki et al. because Toshiba shows the importance of obtaining differing groups of teaching data that correspond with different types of medical examination data, (page 5, lines 10-18) and a person of ordinary skill in the art would understand that teaching data that more closely approximate to the medical examination data would result in better determination of the validity of the present medical examination data. Therefore, one of

ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

Claims 18, 19, 21-27, 29 and 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al., (EP 0389992) as applied to claims 18, 19, 22-27 and 30-33 above, in view of Kataoka et al. (Transactions of Information Processing Society of Japan, 2001, 15 September, 92-99), IDS, received 11 January 2006.

The instant claims 21 and 29 depend from claims 18 and 26 respectively, with the extra limitation that the reference patterns include waveform data.

Toshiba is applied to claims 18, 19, 22-27 and 30-33 above.

Toshiba does not show reference patterns that include waveform data.

Kataoka et al. shows the relationships between patterns of waveform data and medical data, (abstract).

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to modify the method and system of confirming a validity of result of clinical examination of a part of a subject for a clinical examination by Toshiba by comparing the medical examination data with patterns of waveform data of Kataoka et al. because Toshiba shows the importance of obtaining differing groups of teaching data that correspond with different types of medical examination data, (page 5, lines 10-18) and a person of ordinary skill in the art would understand that teaching data that more closely approximate to the medical examination data would result in better determination of the validity of the present medical examination data. Therefore, one of

ordinary skill in the art would recognize the claimed process as a combination of routine applications that are well known the art that and produce no more than expected results.

Claim 18, 19, 22-27 and 30-34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Toshiba et al., (EP 0389992) as applied to claims 18, 19, 22-27 and 30-33 above.

The instant claim is drawn to a computer readable medium carrying instructions for confirming a validity of result of clinical examination of a part of a subject for a clinical examination comprising steps of receiving present and previous data, storing a plurality of reference patterns classified into a plurality of levels, selecting a reference pattern matching the present data and previous data, calculating a value indicative of a distance between a position between the reference patterns and determining a validity of the present data.

In *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958), the court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplish the same result is not sufficient to distinguish over the prior art (see also *Manual of Patent Examining Procedure,* U.S. Trademark and Patent Office, section 2144.04, III).

In the instant case, the claimed invention merely makes the process of Toshiba as computer-implemented or automatic and indeed accomplishes the same result. It is thus not sufficient to distinguish over Toshiba. Therefore, the claimed invention, i.e. the

computer readable medium comprising instructions to execute a process would have been obvious to a person of ordinary skill in the art at the time the invention was made over the process disclosed by Toshiba.

Furthermore, while Toshiba does not explicitly disclose such a computer medium comprising instructions for executing all the steps of the process as in claims 26, it does disclose an apparatus for automatically analyzing validity of medical examination data, (abstract). Thus, the entire method of Toshiba could be interpreted as automatic. One of ordinary skill in the art would have been motivated to provide instructions in a computer readable medium for executing all steps of the method to take the obvious advantage of a fully automatic process, i.e. saving time and cost.

There would have been a reasonable expectation of success because the court held regarding software that "writing code for such software is within the skill of the art, not requiring undue experimentation, once its functions have been disclosed." Fonar Corp., 107 F.3d at 1549, 41 USPQ2d at 1805.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY D. RIGGS II whose telephone number is (571)270-3062. The examiner can normally be reached on Monday-Thursday, 7:30AM-5:00PM, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/ERIC S. DEJONG/
Primary Examiner, Art Unit 1631

/LDR/
Larry D. Riggs II
Examiner, Art Unit 1631